

**REMARKS**

In the present communication, claims 1, 9, 10, 12 and 17 are amended; claims 3, 4, 7, 8, 11, 14, 15, 18, 20 and 21 are canceled without prejudice or disclaimer; and claims 23-27 are added. The amendments clarify the claim language and are supported throughout the specification, the Examples, and the claims as originally filed. No new matter has been added. Upon entry of the present amendment, claims 1, 9, 10, 12, 13, 16, 17 and 23-27 will be under consideration.

**Rejection Under 35 U.S.C. §112, First Paragraph, Written Description**

Applicants traverse the rejection of claims 1, 3-4 and 7-16 under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement.

The Office asserts that recital of “hypomethylation is as compared to the half-methylation of the normally imprinted gene” with regard to the H19 gene lacks is not sufficiently described in the specification to fulfill the written description requirement. However, the Office acknowledges that recital of hypomethylation as compared to “normal” half-methylation with regard to a DMR of the IGF2 gene is disclosed and supported by the specification as filed. *See* Office Action at section 7. While not acquiescing to the rationale presented by the Office, Applicants have amended the claims by deleting reference to the H19 gene. As amended, the claims encompasses “hypomethylation...as compared to the half-methylation of the normally imprinted gene” as regards the DMR of the IGF2 gene.

Based on the foregoing, as well as arguments previously submitted on the record, Applicants submit that the subject matter of the amended claims is fully supported by, and disclosed in the specification. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**Rejection Under 35 U.S.C. §112, First Paragraph, Enablement**

Applicants traverse the rejection of claims 1, 3-4, 7-18 and 20 under 35 U.S.C. §112, first paragraph as allegedly not enabled by the specification.

The Office alleges that the specification fails to provide enablement for methods employing detection of hypomethylation in a DMR of the H19 gene as compared to half-methylation of the normally imprinted gene as indicators of loss of imprinting of H19. The Office further alleges that the specification fails to provide enablement for methods employing non-human samples, as well as for detection of risk for cancers other than colorectal cancer. However, the Office acknowledges that the claims are considered enabled with respect to detection of hypomethylation of SEQ ID NO: 1 within the IGF2 gene relative to half-methylation of the “normally imprinted” IGF2 gene. *See* Office Action at section 8. While not acquiescing to the rationale presented in the Office Action, Applicants have amended the claims by deleting reference to the H19 gene. As amended, the claims encompasses “hypomethylation...as compared to the half-methylation of the normally imprinted gene” as regards the DMR of the IGF2 gene. Further, the claims recite that the subject is a human subject, the cancer is colorectal cancer, and the biological sample is a blood sample or a colon mucosa sample, all of which are acknowledged as enabled. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Based on the foregoing, as well as arguments previously submitted on the record, Applicants submit that the amended claims are fully enabled by the specification. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In re Application of:  
Andrew P. Feinberg  
Application No.: 10/629,318  
Filing Date: July 28, 2003  
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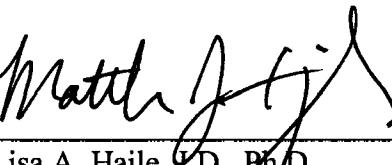
PATENT  
Attorney Docket No. JHU1900-1

### **CONCLUSION**

Applicants submit that the pending claims are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

Applicants believe that no fee is deemed necessary with the filing of this paper. However, the Commissioner is authorized to charge any fees deemed necessary with the filing of this paper, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,

 Reg. No. 53,021  
Lisa A. Haile, J.D., Ph.D.  
Registration No. 38,947  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

Date: December 17, 2010

DLA Piper LLP (US)  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer Number 28213**